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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,148	12/04/2000	Klaus Peter Gerbling	101215-51	2125

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Norris McLaughlin & Marcus
30th Floor
220 East 42nd Street
New York, NY 10017

EXAMINER
EINSMANN, JULIET CAROLINE

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/700,148	GERBLING ET AL.	
	Examiner	Art Unit	
	Juliet C Einsmann	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-27* is/are pending in the application.

4a) Of the above claim(s) *13-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group III in Paper No. 13 is acknowledged. The traversal is on the ground(s) that groups III and IX, drawn to a Salmonella detection kit and method of detecting, respectively, should not be separated because they have unity of invention under the PCT rules. This is not found persuasive because under 37 CFR 1.475(d), "If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims." In the instant case, the first mentioned invention is not a Salmonella detection kit, but a Pseudomonas detection kit. Thus, the Salmonella detection kit is not the main invention in the claims and does not have to be joined to the method of detecting under the unity of invention rules. Furthermore, there is a lack of unity since the elected product claim does not provide a special technical feature over the prior art (see 102 rejections below). PCT Rule 13.2 states "The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes ***over the prior art***. (emphasis added)" Since the detection kit of claim 12 is obvious in view of the prior art (see rejections herein), the kit does not make a contribution over the prior art.

The requirement is still deemed proper and is therefore made FINAL. Claim 12 is examined herein. Applicant is reminded the prior to allowance of claim 12, cancellation of non-elected subject matter will be required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 12 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is indefinite over the recitation "spacers" throughout the claims (for example, line 5, parts (d), (e), (f), and (g). The claims are indefinite in view of this recitation because it is unclear what precisely a "spacer" is. The specification does not define this term. It is unclear if spacers are additional oligonucleotides, or if "spacers" merely represent that the forward and reverse primers would anneal to the target sequence with some unidentified stretch of intervening nucleotides between them . Clarification is requested.

Claim 12 is indefinite because it is not clear what the claimed fragment within the kit must comprise. The claim recites in the preamble that the test kit "comprises at least one DNA fragment comprising the following SEQ IDs and spacers" implying that the fragment must comprise at least the SEQ ID's of parts (a), (b), and (c), but then the later part of the claim states "the DNA fragment, selected from the group of..." implying that the fragment itself is selected from any of the following listed SEQ Ids. It is confusing as to what applicant is trying to claim. Is applicant trying to claim a kit that comprises at least two primers and probe? Is applicant trying to claim a kit that comprises a target sequence that has the to which the primers and probe listed in the claim would hybridize? The claim is narrative and confusing. Clarification is required.

Claim 12 is further indefinite over the use of the parenthetical throughout sections (a)-(g) of the claim. For example (SEQ ID forward primer) in section (a) is confusing because it is not clear if applicant intends for this to represent a SEQ ID in particular, and it is not clear if this is intended to be a positive claim limitation.

Claim 12 is further indefinite in step (g), the language beginning "also comprising variants..." what comprises the variants. It is not clear if the spacer comprise variants, or if the kit itself comprises variants. Furthermore, it is not clear if the variants are required or optional with regard to the claimed kit.

Claim 12 is further indefinite over the recitation "SEQ ID NO: 17 as a reverse primer." This language implies that SEQ ID NO: 17 is to be used as a primer in combination with the forward primer SEQ ID NO: 15. However, SEQ ID NO: 17 is not a reverse primer (i.e. it is not designed to hybridize to the complementary strand of the target) but instead is contained within the same strand as the forward primer in the same orientation as the forward primer SEQ ID NO: 15. Thus, it is confusing what is intended by the statement that SEQ ID NO: 17 is a reverse primer. Amendment of the claim to recite, for example, that the reverse primer consists of an oligonucleotide that is the complement of SEQ ID NO: 17 would obviate this rejection.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boyd *et al.* (Applied and Environmental Microbiology, March 1996, Vol. 62, No. 3, p. 804-808) in view of the Stratagene Catalog (1988).

This rejection applies to claim 12 wherein it is intended to claim a nucleic acid fragment that comprises each of SEQ ID NO: 15, SEQ ID NO: 16 and SEQ ID NO: 17.

Boyd *et al.* teach isolated nucleic acids which comprise the Salmonella invA gene. Boyd *et al.* disclose that the sequences of the genes are given in GenBank Accession numbers, one of these being Accession U43237 (p. 805). This GenBank record enclosed for Applicant's convenience. The sequence taught by Boyd *et al.* is a fragment which comprises instant SEQ ID NO: 15, SEQ ID NO: 16 and SEQ ID NO: 17. Specifically, instant SEQ ID NO: 15 is identical to nucleotides 269-292 of the sequence taught by Boyd *et al.*, SEQ ID NO: 16 is identical to nucleotides 333-356 of the sequence taught by Boyd *et al.*, and SEQ ID NO: 17 is identical to nucleotides 532-555 of the sequence taught by Boyd *et al.*

Boyd *et al.* do not teach a kit which comprises the sequence of the invA gene.

Stratagene teaches gene characterization kits.

It would have been prima facie obvious at the time the invention was made to have included the invA gene taught by Boyd *et al.* in a kit in order to provide a convenient way to distribute the gene to other practitioners interested in studying the Salmonella invA gene. The ordinary practitioner would have been motivated to have produced such a kit because since the Stratagene catalog expressly teaches the benefits to the practitioner of kits:

> "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, pre-mixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control."

It is noted that these claims contain a preamble which recites an intended use, however, it is also noted that this use does not confer patentable weight on the product claims since the preamble does not materially change what is present in the kit itself and thus represents an intended use of the kit (see MPEP 2111.02). Therefore, the kits of the instant claims are *prima facie* obvious over the disclosure of Boyd *et al.* in view of the Stratagene catalog.

7. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chen *et al.* (International Journal of Food Microbiology 35(1997) 239-250) in view of all of the following: Rhan *et al.* (Molecular and Cellular Probes (1992) Vol. 6, pages 271-279), Bassler *et al.* (Applied and Environmental Microbiology, 1995, Vol. 61, No. 10, pages 3724-3728), Boyd *et al.* (Applied and Environmental Microbiology, March 1996, Vol. 62, No. 3, p. 804-808) and the Stratagene Catalog (1988).

This rejection is applied to claim 12 when claim 12 is interpreted as a claiming a kit which comprises a primer consisting of SEQ ID NO: 15, a probe consisting of SEQ ID NO: 16, and a primer that consists of the complement of SEQ ID NO: 17. These primers and probes are specific to the Salmonella invA gene.

Chen *et al.* teach a pair of primers and a probe for the amplification of the Salmonella invA gene (p. 242). Chen *et al.* teach that the target sequence amplified for the detection of Salmonella was a 287 base pair region of the invA gene as described by Rhan *et al.* (p. 242), except in their study the primer set was modified by the addition of two nucleotides on the reverse primer, and that this modification did not adversely affect the specificity of the primer (p. 247). Chen *et al.* further teach that they used a labeled probe that was designed according to the guidelines of Bassler *et al.* Chen *et al.* are silent as to the precise nucleotide sequence of the primers and probe that they use.

Rhan *et al.* provide a pair of oligonucleotide primers for the amplification of a portion of the Salmonella invA gene. The primer taught by Rhan *et al.* as 139 comprises instant SEQ ID NO: 15 in its entirety. The primer taught by Rhan *et al.* differs from instant SEQ ID NO: 15 only in that it comprises an additional two nucleotides at the 3' end (Table 3 of Rhan *et al.*, p. 275). The primer taught by Rhan *et al.* as is identical to the complement of SEQ ID NO: 17 except that the complement of instant SEQ ID NO: 17 has an additional two nucleotides on the 5' end (see Table 3 of Rhan *et al.*, p. 275).

Bassler *et al.* provide general guidance for the selection of probes for use in the TaqMan methods, such as those being employed by Chen *et al.* Bassler *et al.* teach that such guidelines include "keeping the G+C content in the 40 to 60% range and avoiding extensive hairpins of

self-complementary regions. Runs of identical nucleotides, especially G's and extensive regions of complementary between probe and either PCR primer should be avoided. The prove should be designed so that the predicted Tm is at least 5°C higher than the Tm of the PCR primers. Finally a G should not be the 5'-end nucleotide (p. 3725)."

Boyd *et al.* teach isolated nucleic acids which comprise the Salmonella invA gene. Boyd *et al.* disclose that the sequences of the genes are given in GenBank Accession numbers, one of these being Accession U43237 (p. 805). This GenBank record enclosed for Applicant's convenience. The sequence taught by Boyd *et al.* is a fragment which comprises instant SEQ ID NO: 15, SEQ ID NO: 16 and SEQ ID NO: 17. Specifically, instant SEQ ID NO: 15 is identical to nucleotides 269-292 of the sequence taught by Boyd *et al.*, SEQ ID NO: 16 is identical to nucleotides 333-356 of the sequence taught by Boyd *et al.*, and SEQ ID NO: 17 is identical to nucleotides 532-555 of the sequence taught by Boyd *et al.*

Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have provided a pair of primers and a probe which comprise a primer consisting of SEQ ID NO: 15, a probe consisting of SEQ ID NO: 16, and a primer that consists of the complement of SEQ ID NO: 17. The ordinary practitioner would have been motivated to provide such a set by the roadmap provided by the teachings of Chen *et al.*, Rhan *et al.*, Bassler *et al.*, and Boyd *et al.* The ordinary practitioner would have been motivated to select a primer pair consisting of SEQ ID NO: 15 and the complement of SEQ ID NO: 17 because such a primer pair is only very minimally modified from the primer pair taught by Rhan *et al.* (as cited by Chen *et al.*), and Chen *et al.* specifically teach that the addition of two nucleotides to the end of the reverse primer taught by Rhan *et al.* did not result in impairment of the ability of the primer to

function. Furthermore, the ordinary practitioner would have been motivated to select any probe from within the 287 base pair amplicon amplified by such primers. Such a selection would have been motivated by the combined teachings of Chen *et al.*, Bassler *et al.*, and Boyd *et al.* Chen *et al.* specifically state that they used an oligonucleotide probe selected using the guidelines provided by Bassler *et al.*, Bassler *et al.* provide clear guidance for the selection of a probe, and Boyd *et al.* provide the entire sequence of the amplified region of the invA gene from which to select a probe. The ordinary practitioner would have been motivated to select any probe from with the 287 base pair amplified region that met the clear guidance provided by Bassler *et al.* to be provided with the primers for the detection of Salmonella.

Chen *et al.*, Rhan *et al.*, Bassler *et al.*, and Boyd *et al.* do not teach kits.

Stratagene teaches gene characterization kits.

It would have been prima facie obvious at the time the invention was made to have included the primers and probes to the Salmonella invA gene taught by Chen *et al.*, Rhan *et al.*, Bassler *et al.*, and Boyd *et al.* in a kit in order to provide a convenient way to distribute the gene to other practitioners interested in detecting the Salmonella. The ordinary practitioner would have been motivated to have produced such a kit because since the Stratagene catalog expressly teaches the benefits to the practitioner of kits:

> "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, pre-mixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control."

Therefore, the kits of the instant claims are *prima facie* obvious over the disclosure of Chen *et al.*, Rhan *et al.*, Bassler *et al.*, and Boyd *et al.* in view of the Stratagene catalog.

Conclusion

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Juliet C. Einsmann
Examiner
Art Unit 1634

March 19, 2003

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600